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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,901	05/27/2005	Yasuhiko Onishi	052603	6263

38834 7590 05/13/2008

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EXAMINER	
HEINCER, LIAM J	

ART UNIT	PAPER NUMBER
1796	

MAIL DATE	DELIVERY MODE
05/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,901	ONISHI, YASUHIKO	
	Examiner	Art Unit	
	Liam J. Heincer	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

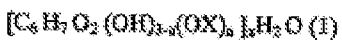
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

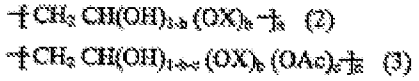
> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Onishi (US Pat. 4,816,540).

Considering Claim 1: Onishi teaches a latex/aqueous solution (1:37-42) comprising cationic graft-copolymer (1:1) of a water-soluble linear backbone polymer having hydroxyl groups (2:6-10) comprising a unit derived from a cationic water-soluble linear polysaccharide of the following formula (1)

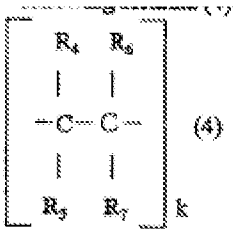


or a unit derived from a water-soluble linear polyvinyl alcohol of the following formula (2) or a partial hydrolyzed alcohol of the following formula (3)



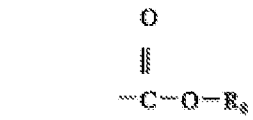
Wherein X is a -- $(CH_2)_mR_1$ organic radical where R_1 is a member of the class consisting of -- NH_2 radical, -- $N(CH_3)_2$ radical, -- $N(C_2H_5)_2$ radical, -- $N^+(C_2H_5)_3$ radical, -- $N^+(CH_2)_2CH_2CH(OH)CH_3$ radical, -- $N^+(C_2H_5)_2CH_2CH(OH)CH_3$ radical, -- $N^+(C_2H_5)_2(C_2H_5)N(C_2H_5)_2$ radical, -- $C_6H_4NH_2$ radical, and – $COC_6H_4NH_2$ radical, -- COR_2 radical where R_2 is -- CH_2NH_2 or -- $C_6H_4NH_2$, -- $CH_2CH(OH)CH_2R_3$ radical where R_3 is --NH_2, --$N(CH_3)_2$, --$N(C_2H_5)_2$, and –$N^+(C_2H_5)_3$ radical, m is a natural number of 1 to 3, a is a positive number having a value of $0<a<3$, b is a positive number having a value of $0<b<1$, and Ac is acetyl radical (2:13-44); and a unit derived from a polymerize-able

olefin compound of the following formula (4)

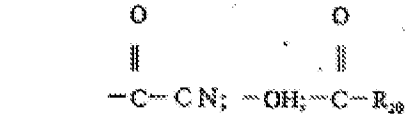


(4)

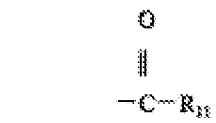
Wherein R_4, R_5 and R_6 are each selected from the group consisting of hydrogen and CH_3 and R_7 is a member of the group consisting of



Where R_8 is a member of the class consisting of hydrogen, C_1-C_{12} alkyl radicals, cyclohexyl radical, C_1-C_4 hydroxyalkyl radicals, C_1-C_8 aminoalkyl radicals, C_1-C_8 dialkylaminoalkyl radicals, glycidyl radical, tetrahydrofuran radical, C_1-C_4 lower alkyl – substituted tetrahydrofuran radical, benzyl radical, the $(CH_2CH_2O)_yCH_2CH_2OH$ radical where y is a positive integer from 1 to 10,and--$N(R_9)_2$ where the two R_9's which may be the same or different, are either hydrogen or a C_1-C_4 alkyl radical;



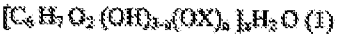
Where R_{10} is a C_1- C_8 alkyl radical; phenyl radical; tolyl radical; pyridine radical; pyrrolidone radical; and



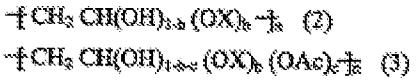
Where R_{11} is NH_2, $NHCH_3$, N,N-dimethylamino radical, N,N-dimethylaminopropylamino radical, and morpholine radical (2:66-3:39). The limitation "for a non-viral gene delivery vector" is functional language that does not materially change the structure of the polymer.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Onishi (US Pat. 4,816,540).

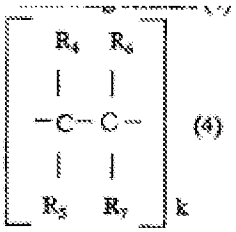
Considering Claim 2: Onishi teaches a process for preparing a latex/aqueous solution (1:37-42) comprising cationic graft-copolymer (1:27-31) of a water-soluble linear backbone polymer having hydroxyl groups (2:6-10) comprising a unit derived from a cationic water-soluble linear polysaccharide of the following formula (1)



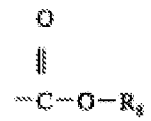
or a unit derived from a water-soluble linear polyvinyl alcohol of the following formula (2) or a partial hydrolyzed alcohol of the following formula (3)



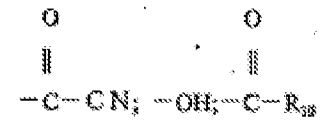
Wherein X is a -- $(CH_2)_mR_1$ organic radical where R_1 is a member of the class consisting of -- NH_2 radical, -- $N(CH_3)_2$ radical, -- $N(C_2H_5)_2$ radical, -- $N^+(C_2H_5)_3$ radical, -- $N^+(CH_2)_2CH_2CH(OH)CH_3$ radical, -- $N^+(C_2H_5)_2CH_2CH(OH)CH_3$ radical, -- $N^+(C_2H_5)_2(C_2H_5)N(C_2H_5)_2$ radical, -- $C_6H_4NH_2$ radical, and – $COC_6H_4NH_2$ radical, -- COR_2 radical where R_2 is -- CH_2NH_2 or -- $C_6H_4NH_2$, -- $CH_2CH(OH)CH_2R_3$ radical where R_3 is --NH_2, --$N(CH_3)_2$, --$N(C_2H_5)_2$, and –$N^+(C_2H_5)_3$ radical, m is a natural number of 1 to 3, a is a positive number having a value of 0<a<3, b is a positive number having a value of 0<b<1, and Ac is acetyl radical (2:13-44); and a unit derived from a polymerize-able olefin compound of the following formula (4)



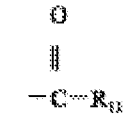
Wherein R_4, R_5 and R_6 are each selected from the group consisting of hydrogen and CH_3 and R_7 is a member of the group consisting of



Where R_8 is a member of the class consisting of hydrogen, C_1-C_{12} alkyl radicals, cyclohexyl radical, C_1-C_4 hydroxyalkyl radicals, C_1-C_8 aminoalkyl radicals, C_1-C_8 dialkylaminoalkyl radicals, glycidyl radical, tetrahydrofuran radical, C_1-C_4 lower alkyl – substituted tetrahydrofuran radical, benzyl radical, the $(CH_2CH_2O)_yCH_2CH_2OH$ radical where y is a positive integer from 1 to 10,and--$N(R_9)_2$ where the two R_9's which may be the same or different, are either hydrogen or a C_1-C_4 alkyl radical;



Where R_{10} is a C_1- C_8 alkyl radical; phenyl radical; tolyl radical; pyridine radical; pyrrolidone radical; and



Where R_{11} is NH_2, $NHCH_3$, N,N-dimethylamino radical, N,N-dimethylaminopropylamino radical, and morpholine radical (2:66-3:39). The limitation "for a non-viral gene delivery vector" is functional language that does not materially change the structure of the polymer.

Claim Rejections - 35 USC § 103

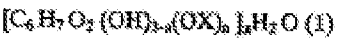
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

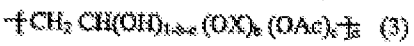
invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onishi (US Pat. 4,816,540) in view of Pack, Gene-Delivery Polymers.

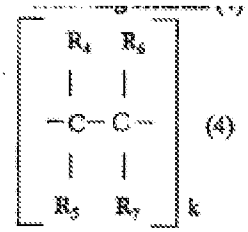
Considering Claim 3: Onishi teaches a cationic graft-copolymer (1:1) of a water-soluble linear backbone polymer having hydroxyl groups (2:6-10) comprising a unit derived from a cationic water-soluble linear polysaccharide of the following formula (1)



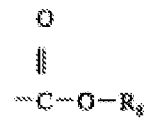
or a unit derived from a water-soluble linear polyvinyl alcohol of the following formula (2) or a partial hydrolyzed alcohol of the following formula (3)



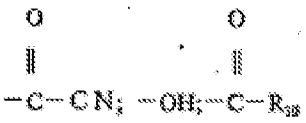
Wherein X is a -- $(CH_2)_mR_1$ organic radical where R_1 is a member of the class consisting of -- NH_2 radical, -- $N(CH_3)_2$ radical, -- $N(C_2H_5)_2$ radical, -- $N^+(C_2H_5)_3$ radical, -- $N^+(CH_2)_2CH_2CH(OH)CH_3$ radical, -- $N^+(C_2H_5)_2CH_2CH(OH)CH_3$ radical, -- $N^+(C_2H_5)_2(C_2H_5)N(C_2H_5)_2$ radical, -- $C_6H_4NH_2$ radical, and – $COC_6H_4NH_2$ radical, -- COR_2 radical where R_2 is -- CH_2NH_2 or -- $C_6H_4NH_2$, -- $CH_2CH(OH)CH_2R_3$ radical where R_3 is --NH_2, --$N(CH_3)_2$, --$N(C_2H_5)_2$, and –$N^+(C_2H_5)_3$ radical, m is a natural number of 1 to 3, a is a positive number having a value of 0<a<3, b is a positive number having a value of 0<b<1, and Ac is acetyl radical (2:13-44); and a unit derived from a polymerize-able olefin compound of the following formula (4)



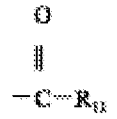
Wherein R_4, R_5 and R_6 are each selected from the group consisting of hydrogen and CH_3 and R_7 is a member of the group consisting of



Where R_8 is a member of the class consisting of hydrogen, C_1-C_{12} alkyl radicals, cyclohexyl radical, C_1-C_4 hydroxyalkyl radicals, C_1-C_8 aminoalkyl radicals, C_1-C_8 dialkylaminoalkyl radicals, glycidyl radical, tetrahydrofuran radical, C_1-C_4 lower alkyl – substituted tetrahydrofuran radical, benzyl radical, the $(CH_2CH_2O)_yCH_2CH_2OH$ radical where y is a positive integer from 1 to 10,and--$N(R_9)_2$ where the two R_9's which may be the same or different, are either hydrogen or a C_1-C_4 alkyl radical;



Where R_{10} is a C_1- C_8 alkyl radical; phenyl radical; tolyl radical; pyridine radical; pyrrolidone radical; and



Where R_{11} is NH_2, $NHCH_3$, N,N-dimethylamino radical, N,N-dimethylaminopropylamino radical, and morpholine radical (2:66-3:39). The limitation "for a non-viral gene delivery vector" is functional language that does not materially change the structure of the polymer.

Onishi does not teach forming a complex with DNA. However, Pack teaches forming a complex between a cationic graft polymer and DNA (Section 2.2.2). Onishi and Pack are combinable as they are concerned with the same field of endeavor, namely cationic polymers. It would have been obvious to a person having ordinary skill in the art at the time of the invention to have formed a complex between the polymer of Onishi and DNA as in Pack, and the motivation to do so would have been, as Pack suggests, to form a complex for use in gene therapy (Section 2.2).

Considering Claim 5: Onishi does not teach a gene delivery system. However, Pack teaches forming a gene delivery system from a complex between a cationic graft polymer and DNA (Section 2.2.2). It would have been obvious to a person having ordinary skill in the art at the time of the invention to have formed the gene delivery system from the polymer of Onishi as in Pack, and the motivation to do so would have been, as Pack suggests, to treat disease with gene therapy (Section 1).

Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onishi (US Pat. 4,816,540) in view of Pack, Gene-Delivery Polymers.

Considering Claim 4: Onishi teaches a cationic graft-copolymer (1:1) of a water-soluble linear backbone polymer having hydroxyl groups (2:6-10) comprising a unit derived from a cationic water-soluble linear polysaccharide of the following formula (1)

$$[C_6H_7O_2(OH)_{3-a}(OX)_a]_nH_2O \quad (1)$$

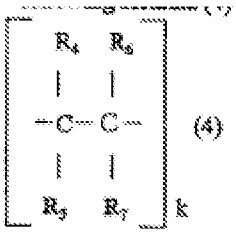
or a unit derived from a water-soluble linear polyvinyl alcohol of the following formula (2) or a partial hydrolyzed alcohol of the following formula (3)

$$+CH_2CH(OH)_{1-a}(OX)_a+_n \quad (2)$$

$$+CH_2CH(OH)_{1-a-b}(OX)_a(OAc)_b+_n \quad (3)$$

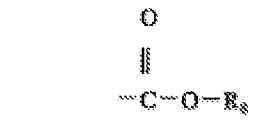
Wherein X is a -- $(CH_2)_mR_1$ organic radical where R_1 is a member of the class consisting of -- NH_2 radical, -- $N(CH_3)_2$ radical, -- $N(C_2H_5)_2$ radical, -- $N^+(C_2H_5)_3$ radical, -- $N^+(CH_2)_2CH_2CH(OH)CH_3$ radical, -- $N^+(C_2H_5)_2CH_2CH(OH)CH_3$ radical, -- $N^+(C_2H_5)_2(C_2H_5)N(C_2H_5)_2$ radical, -- $C_6H_4NH_2$ radical, and – $COC_6H_4NH_2$ radical, -- COR_2 radical where R_2 is -- CH_2NH_2 or -- $C_6H_4NH_2$, -- $CH_2CH(OH)CH_2R_3$ radical where R_3 is --NH_2, --$N(CH_3)_2$, --$N(C_2H_5)_2$, and $-N^+(C_2H_5)_3$ radical, m is a natural number of 1 to 3, a is a positive number having a value of $0<a<3$, b is a positive number having a value of $0<b<1$, and Ac is acetyl radical (2:13-44); and a unit derived from a polymerize-able

olefin compound of the following formula (4)

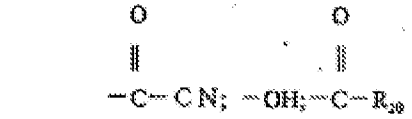


(4)

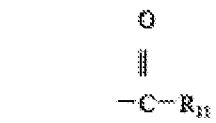
Wherein R_4, R_5 and R_6 are each selected from the group consisting of hydrogen and CH_3 and R_7 is a member of the group consisting of



Where R_8 is a member of the class consisting of hydrogen, C_1-C_{12} alkyl radicals, cyclohexyl radical, C_1-C_4 hydroxyalkyl radicals, C_1-C_8 aminoalkyl radicals, C_1-C_8 dialkylaminoalkyl radicals, glycidyl radical, tetrahydrofuran radical, C_1-C_4 lower alkyl – substituted tetrahydrofuran radical, benzyl radical, the $(CH_2CH_2O)_yCH_2CH_2OH$ radical where y is a positive integer from 1 to 10,and--$N(R_9)_2$ where the two R_9's which may be the same or different, are either hydrogen or a C_1-C_4 alkyl radical;



Where R_{10} is a C_1- C_8 alkyl radical; phenyl radical; tolyl radical; pyridine radical; pyrrolidone radical; and



Where R_{11} is NH_2, $NHCH_3$, N,N-dimethylamino radical, N,N-dimethylaminopropylamino radical, and morpholine radical (2:66-3:39). The limitation "for a non-viral gene delivery vector" is functional language that does not materially change the structure of the polymer.

Onishi does not teach forming a complex with RNA. However, Pack teaches forming a complex between a cationic graft polymer and RNA (Sections 2.2.2 and 2.2). Onishi and Pack are combinable as they are concerned with the same field of endeavor, namely cationic polymers. It would have been obvious to a person having ordinary skill in the art at the time of the invention to have formed a complex between the polymer of Onishi and RNA as in Pack, and the motivation to do so would have been, as Pack suggests, to form a complex for use in gene therapy (Section 2.2).

Considering Claim 6: Onishi does not teach a gene delivery system. However, Pack teaches forming a gene delivery system from a complex between a cationic graft polymer and RNA (Sections 2.2.2 and 2.2). It would have been obvious to a person having ordinary skill in the art at the time of the invention to have formed the gene delivery system from the polymer of Onishi as in Pack, and the motivation to do so would have been, as Pack suggests, to treat disease with gene therapy (Section 1).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

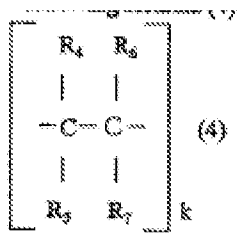
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 4,816,540 in view of Pack, Gene-Delivery Polymers.

Considering Claim 1: Patent '540 teaches a cationic graft-copolymer of a water-soluble linear backbone polymer having hydroxyl groups comprising a unit derived from a cationic water-soluble linear polysaccharide of the following formula (1)

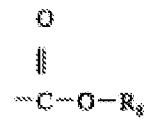
$[C_6H_7O_2(OH)_{3-a}(OX)_a]_bH_2O$ (1)

Wherein X is a $--(CH_2)_mR_1$ organic radical where R_1 is a member of the class consisting of -- NH_2 radical, -- $N(CH_3)_2$ radical, -- $N(C_2H_5)_2$ radical, -- $N^+(C_2H_5)_3$ radical, -- $N^+(CH_2)_2CH_2CH(OH)CH_3$ radical, -- $N^+(C_2H_5)_2CH_2CH(OH)CH_3$ radical, -- $N^+(C_2H_5)_2(C_2H_5)N(C_2H_5)_2$ radical, -- $C_6H_4NH_2$ radical, and – $COC_6H_4NH_2$ radical, -- COR_2 radical where R_2 is -- CH_2NH_2 or -- $C_6H_4NH_2$, -- $CH_2CH(OH)CH_2R_3$ radical where R_3 is $--NH_2$, $--N(CH_3)_2$, $--N(C_2H_5)_2$, and $–N^+(C_2H_5)_3$ radical, m is a natural number of 1 to 3, a is a positive number having a value of $0<a<3$, b is a positive number having a value of $0<b<1$, and Ac is acetyl radical; and a unit derived from a polymerize-able olefin compound of the following formula (4)

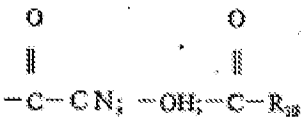


(4)

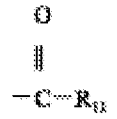
Wherein R_4, R_5 and R_6 are each selected from the group consisting of hydrogen and CH_3 and R_7 is a member of the group consisting of



Where R_8 is a member of the class consisting of hydrogen, C_1-C_{12} alkyl radicals, cyclohexyl radical, C_1-C_4 hydroxyalkyl radicals, C_1-C_8 aminoalkyl radicals, C_1-C_8 dialkylaminoalkyl radicals, glycidyl radical, tetrahydrofuran radical, C_1-C_4 lower alkyl – substituted tetrahydrofuran radical, benzyl radical, the $(CH_2CH_2O)_yCH_2CH_2OH$ radical where y is a positive integer from 1 to 10,and--$N(R_9)_2$ where the two R_9's which may be the same or different, are either hydrogen or a C_1-C_4 alkyl radical;



Where R_{10} is a C_1- C_8 alkyl radical; phenyl radical; tolyl radical; pyridine radical; pyrrolidone radical; and

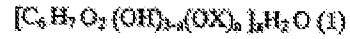


Where R_{11} is NH_2, $NHCH_3$, N,N-dimethylamino radical, N,N-dimethylaminopropylamino radical, and morpholine radical (Claim 1).

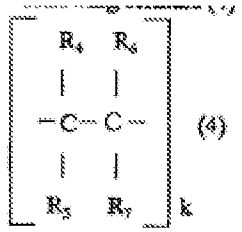
Patent '540 does not teach the polymer as being in an aqueous solution. However, Pack teaches using a DEAE-dextran copolymer in vivo/in an aqueous solution (Section 2.2). Patent '540 and Pack are combinable as they are concerned with the same field of endeavor, namely cationic polymers. It would have been obvious to a person having ordinary skill in the art at the time of invention to have put the DEAE-dextran polymer of Patent '540 in an aqueous solution as in Pack, and the motivation to do so would have been, as Pack suggests, it will allow the polymer to be used in gene delivery applications (Section 2.2).

Claim 2 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 4,816,540.

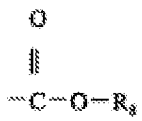
Considering Claim 2: Patent '540 teaches process for preparing a cationic graft-copolymer of a water-soluble linear backbone polymer having hydroxyl groups comprising a unit derived from a cationic water-soluble linear polysaccharide of the following formula (1)



Wherein X is a -- $(CH_2)_mR_1$ organic radical where R_1 is a member of the class consisting of -- NH_2 radical, -- $N(CH_3)_2$ radical, -- $N(C_2H_5)_2$ radical, -- $N^+(C_2H_5)_3$ radical, -- $N^+(CH_2)_2CH_2CH(OH)CH_3$ radical, -- $N^+(C_2H_5)_2CH_2CH(OH)CH_3$ radical, -- $N^+(C_2H_5)_2(C_2H_5)N(C_2H_5)_2$ radical, -- $C_6H_4NH_2$ radical, and – $COC_6H_4NH_2$ radical, -- COR_2 radical where R_2 is -- CH_2NH_2 or -- $C_6H_4NH_2$, -- $CH_2CH(OH)CH_2R_3$ radical where R_3 is --NH_2, --$N(CH_3)_2$, --$N(C_2H_5)_2$, and $-N^+(C_2H_5)_3$ radical, m is a natural number of 1 to 3, a is a positive number having a value of 0<a<3, b is a positive number having a value of 0<b<1, and Ac is acetyl radical (2:13-44); and a unit derived from a polymerize-able olefin compound of the following formula (4)

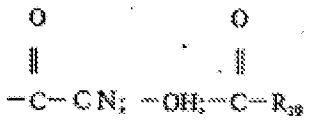


Wherein R_4, R_5 and R_6 are each selected from the group consisting of hydrogen and CH_3 and R_7 is a member of the group consisting of

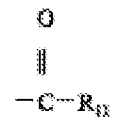


Where R_8 is a member of the class consisting of hydrogen, C_1-C_{12} alkyl radicals, cyclohexyl radical, C_1-C_4 hydroxyalkyl radicals, C_1-C_8 aminoalkyl radicals, C_1-C_8 dialkylaminoalkyl radicals, glycidyl radical, tetrahydrofuran radical, C_1-C_4 lower alkyl –

substituted tetrahydrofuran radical, benzyl radical, the $(CH_2CH_2O)_yCH_2CH_2OH$ radical where y is a positive integer from 1 to 10,and--$N(R_9)_2$ where the two R_9's which may be the same or different, are either hydrogen or a C_1-C_4 alkyl radical;



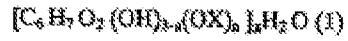
Where R_{10} is a C_1- C_8 alkyl radical; phenyl radical; tolyl radical; pyridine radical; pyrrolidone radical; and



Where R_{11} is NH_2, $NHCH_3$, N,N-dimethylamino radical, N,N-dimethylaminopropylamino radical, and morpholine radical (Claim 2). As a process claim is determined by the process steps claimed, not necessarily the product made, the claim limitations are considered met.

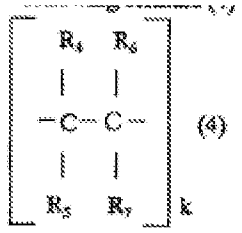
Claims 3-6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 4,816,540 in view of Pack, Gene-Delivery Polymers.

Considering Claims 4 and 5: Patent '540 teaches a cationic graft-copolymer of a water-soluble linear backbone polymer having hydroxyl groups comprising a unit derived from a cationic water-soluble linear polysaccharide of the following formula (1)



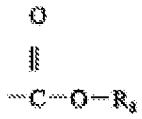
Wherein X is a --$(CH_2)_mR_1$ organic radical where R_1 is a member of the class consisting of -- NH_2 radical, -- $N(CH_3)_2$ radical, -- $N(C_2H_5)_2$ radical, -- $N^+(C_2H_5)_3$ radical, -- $N^+(CH_2)_2CH_2CH(OH)CH_3$ radical, -- $N^+(C_2H_5)_2CH_2CH(OH)CH_3$ radical, -- $N^+(C_2H_5)_2(C_2H_5)N(C_2H_5)_2$ radical, -- $C_6H_4NH_2$ radical, and – $COC_6H_4NH_2$ radical, -- COR_2 radical where R_2 is -- CH_2NH_2 or -- $C_6H_4NH_2$, -- $CH_2CH(OH)CH_2R_3$ radical where R_3 is --NH_2, --$N(CH_3)_2$, --$N(C_2H_5)_2$, and –$N^+(C_2H_5)_3$ radical, m is a natural number of 1 to

3, a is a positive number having a value of 0<a<3, b is a positive number having a value of 0<b<1, and Ac is acetyl radical; and a unit derived from a polymerize-able olefin compound of the following formula (4)

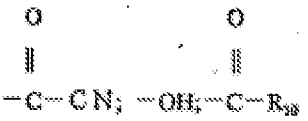


(4)

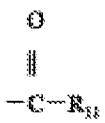
Wherein R_4, R_5 and R_6 are each selected from the group consisting of hydrogen and CH_3 and R_7 is a member of the group consisting of



Where R_8 is a member of the class consisting of hydrogen, C_1-C_{12} alkyl radicals, cyclohexyl radical, C_1-C_4 hydroxyalkyl radicals, C_1-C_8 aminoalkyl radicals, C_1-C_8 dialkylaminoalkyl radicals, glycidyl radical, tetrahydrofuran radical, C_1-C_4 lower alkyl – substituted tetrahydrofuran radical, benzyl radical, the $(CH_2CH_2O)_yCH_2CH_2OH$ radical where y is a positive integer from 1 to 10,and--$N(R_9)_2$ where the two R_9's which may be the same or different, are either hydrogen or a C_1-C_4 alkyl radical;



Where R_{10} is a C_1- C_8 alkyl radical; phenyl radical; tolyl radical; pyridine radical; pyrrolidone radical; and



Where R_{11} is NH_2, $NHCH_3$, N,N-dimethylamino radical, N,N-dimethylaminopropylamino radical, and morpholine radical (Claim 1).

Patent '540 does not teach forming a complex with DNA or RNA. However, Pack teaches forming a complex between a cationic graft polymer and DNA or RNA (Sections 2.2.2 and 2.2). Patent '540 and Pack are combinable as they are concerned with the same field of endeavor, namely cationic polymers. It would have been obvious to a person having ordinary skill in the art at the time of the invention to have formed a complex between the polymer of Patent '540 and DNA or RNA as in Pack, and the motivation to do so would have been, as Pack suggests, to form a complex for use in gene therapy (Section 2.2).

Considering Claims 5 and 6: Patent '540 does not teach a gene delivery system. However, Pack teaches forming a gene delivery system from a complex between a cationic graft polymer and DNA or RNA (Sections 2.2.2 and 2.2). It would have been obvious to a person having ordinary skill in the art at the time of the invention to have formed the gene delivery system from the polymer of Patent '540 as in Pack, and the motivation to do so would have been, as Pack suggests, to treat disease with gene therapy (Section 1).

Response to Arguments

Applicant's arguments filed December 19, 2007 have been fully considered but they are not persuasive, because:

A) Applicant's argument that Onishi does not teach an aqueous solution is not persuasive. Onishi teaches a latex comprising the cationic graft polymer (1:37-42). A latex is by definition an aqueous solution comprising a polymeric substance.

B) Applicant's argument that a person having ordinary skill in the art at the time of invention would not have found it obvious to have used the polymer of Onishi et al. in a gene delivery vector is not persuasive. As Pack teaches, it is well known to use cationic DEAE-dextran polymers in gene delivery vectors as they have been used extensively sine the 1960s (Section 2.2). Additionally Pack teaches that synthetic vectors provide improved safety, greater flexibility and more facile manufacturing (Section 2.2). Finally, as Onishi teaches that the grafted DEAE-dextran is able to ionicly bind anionic biopolymers (namely proteins) due to its anionic nature (1:53-58) and Pack

teaches that synthetic gene delivery vectors electrostatically bind DNA and RNA (Section 2.2), a person having ordinary skill in the art at the time of invention would have found it obvious to try the grafted DEAE-dextran polymer as a gene delivery vector.

C) Applicants argument that the polymer of the instant invention is superior to the prior art polymers in terms of transfection is not persuasive. The effectiveness of the current invention, in the absence of a showing of unexpected results, is not enough to overcome a prima facie of obviousness.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liam J. Heincer whose telephone number is 571-270-3297. The examiner can normally be reached on Monday thru Friday 7:30 to 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARK EASHOO/ LJH
Supervisory Patent Examiner, Art Unit 1796 May 2, 2008
10-May-08